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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/523,681

09/23/2005

Gerald McMorrow

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EXAMINER

LAMPRECHT, JOEL

ART UNIT

PAPER NUMBER

3737

NOTIFICATION DATE

DELIVERY MODE

05/13/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/523,681	Applicant(s) MCMORROW ET AL.	
	Examiner JOEL M. LAMPRECHT	Art Unit 3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 February 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5,8-30 and 34-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5,8-30 and 34-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-15, and 17-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ganguly et al in view of Bradley et al (US 6,905,467 B2). Ganguly disclose all that is listed above, mainly an apparatus capable of measuring the volume of urine in a bladder of an individual through a non-invasive ultrasound technique including a transducer assembly with a plurality of ultrasound transducers (Fig 4), means for activating the ultrasound transducers (Fig 1), means for determining body cavity height and depth (Col 6 Line 5- Col 8 Line 25), as well as filling degree based on

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known values stored from a patients history (Col 8 Line 35-50). The apparatus also has means for detecting using echo travel time and other beam information, determining which beams intercept the fluid-filled body (Col 4 Line 1 – Col 5 Line 60), display means for display of the calculated fluid volume (Col 8 Line 35-50), means for selecting the number of transducers to indicate bladder filling level (Fig 4, Col 8 Line 15 –50) including a conical beam selection (Col 7 Line 65- Col 8 Line 14), the storage of patient information for the selection of factors for use in volume calculation via a memory (Col 8 Line 35-50), a system provided to adjust the frequency of calculation and display readout (Fig 6, Col 8 Line 35-50), a transducer assembly for locating the walls of the bladder in a single cross-sectional plane (Col 4 Line 35 – Col 5 Line 60), means for showing correct positioning of the transducer assembly (Col 6 Line 30-50), connection to a housing with input device, processor, display, and power supply unit (Fig 6), as well as an ultrasound coupling material covering the transducer for patient convenience (Col 8 Line 25-35). Ganguly et al also disclose mounting the transducer assembly at a predetermined spatial location and angle which can vary over a range (Col 3 Line 15-30), acoustically coupling the transducers to the skin of the patient (Col 8 Line 25-35), using multiple harmonics or frequency measurements from the transducers to establish boundary lines (Col 4 Line 1 – Col 7 Line 65), and include the entirety of the bladder in the ultrasound measurement, using specific frequencies for the establishment of wall features and alternate frequencies for the measurement of the bladder volume, using specific A-lines for the acquisition of data at selected depths including the front/back walls, and the middle of the human bladder (Col 4 Line 1 – Col 7 Line 65), using both

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echo data from approximate front and back wall locations to fit and compute a relative location of the outline or edges of the bladder (Col 4 Line 35-45, Col 6 Line 5-50), and finally establishing a volume, comparing that volume to a predetermined threshold value (Col 8 Line 35-50), storing that value for later comparison (Col 8 Line 35-50), and the use of narrow beams within the piezoelectric elements to produce conventional ultrasound signals.

Ganguly et al do not disclose the use of further harmonic components beyond first harmonic frequency within specific calculations, though inherently, harmonic data for additional harmonic frequencies is backscattered and at least received by the receiving means of both of these disclosures and is used to discern what is "fluid-filled" and wall or other outlying area, as propagation times and therefore frequency of signal are accounted for in both the above recited applications. Attention is therefore directed to the teaching reference to Bradley et al which discloses the use of ultrasound harmonic imaging acquisition (Col 1 Line 5- Col 2 Line 40), calibration (Col 11 Line 54 - Col 12 Line 12), attenuation and difference calculation (Col 11 Line 10- Col 12 Line 12). It would have been obvious to one of ordinary skill in the art to have applied the statistical analysis, ultrasound acquisition windows, and clinical applications of Ganguly et al with the harmonic acquisition imaging system of Bradley et al for the purpose of acquiring the clearest, most accurate image and volumetric measurement of the bladder volume (Col 4 Line 44-Col 5 Line 22).

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ganguly et al in view of Bradley et al (US 6,905,467 B2) as applied to claim 15 above and in further view of Chalana et al (US 7,041,059 B2). Ganguly et al in view of Bradley et al do not disclose providing battery power to the device, attention is then directed to the secondary reference by Chalana which describes a similar diagnostic device using a portable system powered by a battery, and suggests that such a system may be either battery powered or powered conventionally as a matter of choice (Col 4 Line 40 – Col 5 Line 15). Chalana et al describes that a range of frequencies is used, and therefore would have instrumentation to at least acquire reflected signals at harmonic frequencies ($2f = 4 \text{ XHz}$ of 2XHz being $1f$ as an example). It would have been obvious to one of ordinary skill in the art at the time of the invention to have used the battery powered elements of Chalana et al with the bladder volume calculation system of Ganguly in view of Bradley to provide a portable element for approximation of the volume of the fluid in the bladder of a patient.

Response to Arguments

Applicant's arguments filed 2/9/09 have been fully considered but they are not persuasive. Regarding Applicant's argument that harmonic energy levels are not accounted for in the estimation of a fluid volume within the cavity of interest, the reference to Ganguly teaches the estimation of a volume of a bladder without the use of harmonic imaging, and the further reference to the Bradley reference provides teaching of harmonic imaging to discern tissues from one another based on attenuation and reflective properties in order to provide for discernable areas of interest (Col 11 Line 10-

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Col 13 Line 67, Col 15 Line 19-Col 17 Line 67). Bradley allows for a summing or exclusion of certain waveforms received from the sample so as to allow for only acquisition of data relating to specific tissues or fluids being investigated (Col 19 Line 25-Col 24 Line 30). Taking these teachings into account with the methods of Ganguly, one of ordinary skill in the art would simply subtract the voided region from that of the liquid region so as to acquire only a volume of interest (filling level). Such a subtraction becomes nominal when the teachings of Bradley are read in light of the methods of Ganguly.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOEL M. LAMPRECHT whose telephone number is

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(571)272-3250. The examiner can normally be reached on Monday-Friday 8:30AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on (571)272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JML

/BRIAN CASLER/

Supervisory Patent Examiner, Art Unit 3737